UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,201	11/30/2001	Shoujun Chen	13321-007001	8537

26161 7590 02/24/2004

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,201	CHEN ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed on November 3, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schutt (US 4248861). Schutt teaches a skin composition comprising Kava Kava and a carrier (Col. 3, lines 33-41, 48-68; Col. 4, lines 1-5; Col. 5, Examples 3 and 4). This composition is applied to the skin to treat burns and can be prepared in any desired manner and in any suitable order or sequence of addition of the various components (Col. 4, lines 31-44). The Kava Kava is present in amounts from 0.5 to 3 parts by weight (Col. 3, lines 33-41). Schutt further teaches that the Kava Kava extract has an

anesthetic effect (Col. 3, lines 33-41). It is the position of the Examiner that Kava Kava contains all the kavalactones claimed in the instant application.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of the kavalactones. With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization.

One of ordinary skill in the art would have been motivated to do this to provide different dosage levels for different skins types or simply to adjust concentration according to what additional ingredients are included in the composition.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmussen et al. (US 6379696) in combination with Elbakyan (WO 00/30578) further in combination with Schwabe (US 5296224) further in combination with Schutt. Asmussen teaches a transdermal therapeutic system comprising kawain (Col 3- 4, Claim 1).

Asmussen does not expressly teach the patch composition and components of the composition. Asmussen further does not expressly teach that the kawain is used to treat pain.

Elbakyan teaches a transdermal patch composition comprising an active agent in a polymer matrix (Page 6, lines 10-27), an absorbent layer wherein the active composition is supported and a nonabsorbent backing layer (Page 8, lines 13-30).

Elbakyan does not expressly teach a kavalactone as the active agent.

Schwabe teaches that kawain is a kavalactone. Schwabe further teaches other suitable kavalactones such as dihydrokawain, methysticin, dihydromethysticin and yangonin (Col. 1, lines 14-53). Schwabe does not expressly teach that the kavalactones treat pain.

The teachings of Schutt are discussed above. Briefly, Schutt teaches a topical composition comprising Kava Kava extract that contains the specific kavalactones and is used for its anesthetic effect.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a transdermal therapeutic system in the form of a transdermal patch comprising kavalactones for treating pain. Asmussen teaches kawain in a transdermal system. Elbakyan teaches the transdermal system can be in the form of a patch. Schwabe teaches the other suitable kavalactones. Schutt teaches the kavalactones can be used to treat pain.

One of ordinary skill in the art would have been motivated to do this to provide a slow-release therapeutic composition for topical administration in the treatment of skin conditions, whether it is burns or hypertrophic skin accumulations or pain.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schutt in combination with Remington's Pharmaceutical Sciences, 18th Edition, p. 769-70. The teachings of Schutt are discussed above. Schutt's composition includes PABA in the formulation. Schutt does not teach a composition excluding PABA.

Remington's teaches that PABA can be an allergen with side effects such as nausea, anorexia, fever and a rash and incidence of phototoxicity and photoallergenicity can occur.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to remove PABA from ointment compositions. Elimination of an ingredient as well as its function does not impart patentability to a well-known formulation in the absence of said ingredient.

One of ordinary skill in the art would have been motivated to do this to remove the allergen from a composition. One of ordinary skill would remove PABA from a topical skin composition to remove the allergen from the composition to provide a safe product that does not cause an allergic reaction.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection. Applicants argue that the Schutt reference does not teach a composition that comprises the specific kavalactones in the specific concentrations. Further applicants argue that Schutt does not teach a composition or ointment that treats pain. As stated above in this action, the determination of particular concentration ranges is within the skill of the art. The prior art teaches a composition comprising Kava Kava extract that contains all the kavalactones recited in the instant claims. Applicants have shown no unexpected results by selecting these three kavalactones in their particular concentrations. Absent a showing of unexpected results, the instant claims are rendered obvious over the prior art. The Examiner fails to see the criticality in the difference between a composition comprising 1% kavalactones and one comprising 0.4% kavalactones. This difference is a matter of degree and not of kind. As for the treatment of pain, the prior art clearly states that the Kava Kava extract has an anesthetic effect, which is interpreted as a treating pain.

Further, applicants have amended the claims to exclude or minimize the amount of PABA in the topical composition. It is the position of the Examiner that it would be obvious to remove said ingredient from a topical composition because it is known as an allergen. One of ordinary skill would remove such an ingredient to provide a safer provide for a wider number of patients.

Therefore, applicants' arguments are found unpersuasive for the reasons stated herein.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes
Patent Examiner
Art Unit 1615

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600